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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,042

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EXAMINER

MASHACK, MARK F

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

03/22/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,042

Applicant(s)

ZIMMERMANN ET AL.

Examiner

MARK MASHACK

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to a communication dated 1/18/2011. Claims 1-20 are pending.

Response to Arguments

1. Applicant's arguments filed 1/18/2011 have been fully considered but they are not persuasive. Applicant argues that Claim 10 is clear and definite. Examiner disagrees. Claim 1 requires "a basic structure". Claim 10 which dependants on Claim 1 requires "two basic structures". It is unclear if Claim 10 requires three basic structures or if "a basic structure" is divided into "two basic structures" or "a basic structure" is one of the "two basic structures".
2. Applicant argues that "**Das** fails to be directed to the problems associated with placement of an implantable prosthesis in a hernia defect as featured in the present invention." Examiner disagrees. **Das** discloses of a device that meets the claimed limitation and is intended to close an defect in the body. Examiner asserts that it is capable of being inserted into a hernia.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. **Claim 10** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. **Regarding claim 10**, it is unclear how many "basic structures" are required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 1-7, 9-11, 13-20** are rejected under 35 U.S.C. 102(b) as anticipated by **Das (US 5,334,217)** or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Das**

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in view of **Corcoran et al.** ("**Corcoran**" US 6,656,206) and **Evard et al.** ("**Evard**" US 6,616,675).

Das discloses of an implant prosthesis capable of repairing hernia defects comprising a basic structure of mesh fabric (Column 4, Line 61, - Column 5, Line 9) which is deformable into a plug-type insert capable of being positioned in the hernia defect (Fig 2-3), characterized in that the basic structure is a blank of the layer material of a shape preferably ranging from round to oval (Fig 5D); and in that the basic structure in its undeformed position of rest is approximately hourglass-shaped in a plan view (Fig 3). Examiner asserts that the middle portion of **Das** (Fig 3) is capable being "placed in concertina pleats"; however, if that is not convincing, **Corcoran** teaches of the desirability of septal occluders to provide a telescopic feature in order to accommodate tissue of varying thickness (Col 12, Lines 10-22) and **Evard** teaches of a similar telescopic device wherein concertina pleats are used to perform said function (Column 3, Lines 26-40). It would have been obvious to apply these concertina pleats to the device of **Das** in order to allow the device to accommodate different thicknesses of tissue. The basic structure of **Das** comprises a fixing arrangement only approximately central wherein the two halves are joined (Col 7, Lines 49-51). Since the pleats would inherently or obviously be along the middle of the length of the device, the fixing arrangement would pass through said pleats.

Regarding Claim 2-3, the two portions are joined by a fixing thread (Col 7, Lines 49-51). The thread would inherently cross the central pleated portion. **Regarding Claim 5**, the lateral edges can be considered fixed by fixing thread 40. **Regarding Claim 4**

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and **6**, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. **Regarding Claim 7, Das** discloses of a metallic coating (Column 7, Lines 28-32). **Claim 9** is considered a product-by-process. **Regarding Claim 10**, the device comprises two basic structures **22, 32** and are placed crosswise one on top of the other. **Regarding Claim 11**, the blank, not yet pleated, comprises an hourglass shape (Fig 3-4).

Regarding Claim 9, Das or Das in view of **Evard** discloses each and every structural element except for the basic structure being laser beam cut to size. The claimed phrase “the basic structure is laser beam cut to size” is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Regarding Claim 13-15, 17, Das discloses of first and second mesh layers **22, 32** and the pleats as discussed above would inherently or obvious provide a plurality of pleats on each layer joined by the fixing arrangement extending through the fixing arrangement (Col 7, Lines 49-51). **Regarding Claim 16, 20, Das** discloses that the layer material may both comprise a plastic (Col 4, Lines 50-65; nylon). Nylon is also a commonly known material to form a thread. It would have been obvious to form the fixing arrangement of the same material and same thickness since it provides desirable

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thread properties. **Regarding Claim 18**, the two portions are joined by a fixing thread (Col 7, Lines 49-51). The thread would inherently cross the central pleated portion.

Regarding Claim 19, the lateral edges can be considered fixed by fixing thread **40**.

10. **Claims 8, 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Das** in view of **Corcoran** and **Evard** as applied to claim 1 above, and further in view of **Saadat** (US 2003/0018358).

Regarding Claim 8, **Das** or **Das** in view of **Corcoran** and **Evard** disclose all of the claimed limitations including a metallic coating to enhance the radiopacity (**Das**, Column 7, Lines 28-32). However, **Das** does not disclose of the coating comprising titanium. However, **Saadat** teaches of the equivalence of a titanium containing coating and the other metallic coatings. (Paragraph 146). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding Claim 12, **Saadat** teaches of the coating being applied by “sputter coating or ion deposition” and “thin enough layer such that it would not affect the physical properties”. **Saadat** is silent on the actual thickness. It would have been obvious matter of design choice to provide the claimed thickness, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773